K023621 1/2 APR 1 0 2003

Exhibit 19 Summary of Safety & Effectiveness

18 October 2002

The ***BioFlex ™ Professional Therapy System*** is designed for clinical applications to provide low level light therapy and record and display treatment sessions. As such, *this device* is a Class II device, having Regulation Number: ***21 CFR part 890.5500. Product Code NHN and ILY.***

This summary is submitted in behalf of:
Meditech International Inc.
411 Horner Ave., Unit #1,
Etobicoke, Ontario, Canada M8W 4W3
Voice phone number-416 251 1055
Fax phone number- 416 251-2446

This summary is submitted by:
Richard Keen
Compliance Consultants
1151 Hope Street
Stamford, Connecticut, 06907
voice phone number (203) 329 2700)
fax phone number (203) 329 2345.

This device can be **described** as a Class II Low Level Light treatment process employing the application of light, which penetrates the skin surface to the underlying tissues, and triggers normal cellular functions that lead to a surgery-free, drug-free, and low cost benefit to the patient, the practitioner and the health care system. Using proprietary techniques and computational processes. This device is composed of:

- software {that runs in a qualified, ancillary computer},
- proprietary hardware and software, and
- flexible treatment heads.

All ancillary equipment, which works with this device, is identified as a configured item. This device will only be used with specific ancillary equipment, which is tested and qualified to work with ***BioFlex ™ Professional Therapy System***.

The **scientific concept** on which this device is based is the principle that by stimulating a local area with low level light to relieve pain.

The **intended use** of this device is for a trained health care professional to diagnose that specific patients would benefit from this therapy and treat patients for specific ailments using specific protocols.

The "Indications for Use" for this device cover three therapeutic applications:

- relief of neck and shoulder pain, and
- relief of muscle and joint pain, arthritis, muscle spasm, relieving stiffness and promoting relaxation of muscle tissue.

This system is ideally suited for a variety of environments from hospitals to ambulatory settings. The ***BioFlex ™ Professional Therapy System*** allows health care providers to treat, store, select, and display the results of treatments.

This is a *prescription only* device. The labeling, instructions and user operations are designed for health care professionals.

K023621 2/2

Exhibit 19 Summary of Safety & Effectiveness

Meditech International Inc. has determined that the ***BioFlex ™ Professional Therapy System*** is substantially equivalent to the performance of this predicate device:

- **Super Nova ™** via K001179.

This device is different from other predicate devices in that it uses proprietary, interchangeable treatment heads to allow various protocols (and software loaded in a P.C. computer to download protocols) and record session / patient data.

A series of factory calibration tests are conducted to verify the device is accurate and calibrated (and can maintain calibration over its useful life). The ***BioFlex ™ Professional Therapy System*** has benefited from design, development, testing and production procedures that conform to Quality Systems.

This device is safe and effective for the application for which it is intended and has been tested to confirm safety and efficacy. ***Meditech International Inc.*** continues to search all appropriate sources for information relating to safety and effectiveness and maintains an *in-house* reporting system to identify adverse safety and effectiveness information and as such, applicable data is recorded for this product.

CERTIFICATION:
I hereby certify this **Summary of Safety and Effectiveness** applies for the above indicated device.

Dr. Fred Kahn
President
Meditech International Inc.
411 Horner Ave., Unit #1,
Etobicoke, Ontario, Canada M8W 4W3
Voice 416 251 1055
Fax 416 251-2446

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 0 2003

Meditech International, Inc.
c/o Mr. Richard Keen
Compliance Consultants
1151 Hope Street
Stanford, Connecticut 06907

Re: K023621
Trade/Device Name: BioFlex™ Professional Therapy System, US Version
Regulation Number: 21 CFR 890.5500
Regulation Names: Infrared Lamp
Regulatory Class: II
Product Codes: ILY
Dated: February 11, 2003
Received: February 13, 2003

Dear Mr. Keen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K023621

Exhibit 2

510(K) Number (If known): _____510(K) number assigned:K-023621
Device Name: __ *BioFlex Professional Therapy System* [tm]

Indications for Use

The ***BioFlex* [tm] *Professional Therapy System*** is used by trained health care professionals and is indicated for use to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, arthritis, muscle spasm, relieving stiffness and promoting relaxation of muscle tissue.

The ***BioFlex* [tm] *Professional Therapy System*** is a "multi-mode" *low level light* treatment system configured for multiple treatment heads powered by a flexible protocol controller that delivers various treatment protocols.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices
510(k) Number K023621

Prescription Use X
(Per 21 CFR 801.109)

or Over - The - Counter Use _____

(Optional Format 1-2-96)